Wyeth

Submission of Wyeth Canada re:

Proposed Amendments to the Patented Medicines Regulations

("Proposed Amendments")

PART I: INTRODUCTION

This submission is on behalf of Wyeth Canada, and is in response to the Patented Medicine Prices Review Board's ("PMPRB") request for consultation with stakeholders concerning proposed amendments to the *Patented Medicines Regulations, 1994* ("Regulations").

Wyeth Canada is a research-based pharmaceutical company with leading therapeutics in the areas of women's health care, cardiovascular diseases, central nervous system disorders, anti-inflammatory disorders, infectious disease, hemophilia, oncology and vaccines. Wyeth's products include biopharmaceutical products that are the result of significant research and development in the biotechnology field. Since 1883, Wyeth Canada has been making an outstanding, innovative contribution to Canadian healthcare.

In the Proposed Amendments, PMPRB has stated "…the Regulations need to be modernized in some areas to better reflect the information needs of the PMPRB to carry out its responsibilities under the Act". PMPRB further states that, to address stakeholders' concerns regarding improving the timeliness of their price review process, it has determined that "…changing the Regulations to clearly indicate the information that the PMPRB requires for the timely completion of price reviews would be appropriate to propose". The changes presented in the Proposed Amendments are intended to address these concerns of PMPRB.

Wyeth Canada has reviewed the submissions of Rx&D in respect of the Proposed Amendments. Wyeth agrees, in principal, with the Board's assessment that the Regulations require some "housekeeping" activities to remedy some of the changes that have evolved since their last major overhaul in 1994. Wyeth is fully supportive of a number of the proposed amendments; at the same time, Wyeth has concerns about some of the amendments, for which additional clarification is required in order to ascertain how these changes bring value to the prices review process. Without the benefit of additional clarification, Wyeth perceives certain of the proposed amendments to be impractical, unnecessary and potentially contrary to the Patent Act. Wyeth Canada wishes to make the following comments.

PART II: DETAILED FEEDBACK

Sec. 3.1: Notification of Proposed Price

Wyeth Canada believes that the implementation of the proposed amendment, that "…the patentee shall provide prior to the sixtieth day preceding the date on which the patentee first offers the medicine for sale, the price at which the medicine is intended to be sold", is unnecessary, contrary to provisions of the Patent Act, potentially financially detrimental to the patentee, and impractical from a patentee compliance perspective.

If the intent of the Regulation change is to obtain pricing in advance, the Patent Act currently makes allowance for the Board to request the proposed price under Sec. 82(2) which states "… the Board may, by order, require the patentee to provide the Board with information and documents respecting the price at which the medicine is intended to be sold in that market." Clearly the Board already has the power to obtain prices before launch, if required; however, the inclusion of this specific language in the Patent Act implies that requesting the price in advance in this manner would be an unusual event occurring only under unique circumstances, rather than the normal routine as in the proposed amendment. Wyeth questions the value to the Board of receiving advance notification of the 'intent to sell' price, and would request clarification of the purpose for which the Board intends to use this information. Wyeth believes that there are sufficient reporting requirements embedded in existing legislation to facilitate the Board's efficient review of patented medicine prices in a timely manner.

While Sec. 82 (2) of the *Patent Act* gives PMPRB the right to request "… information and documents respecting the price at which the medicine is intended to be sold" Sec. 82 (4) states, "No patentee shall be required to comply with an order made under subsection (2) prior to the sixtieth day preceding the date on which the patentee intends to first offer the medicine for sale". Clearly the implementation of this proposed amendment would position the reporting requirements on patentees in the Regulations in direct contradiction to the intent embodied directly in the Patent Act.

Furthermore, Wyeth is concerned that the uncertainty of accurately anticipating the timing of receipt of NOC may adversely impact the timing of a product launch if we are required to provide 60 days advance notice to PMPRB of our price. Typically, with the exception of confirmation and approval of the final price, most components associated with a new product launch are in place to facilitate the actual launch at or shortly after the NOC is received. Under this proposed amendment, if the NOC is granted more quickly than anticipated, and the 'launch price' has not been filed with PMPRB in accordance with the proposed regulations, this may necessitate a delay in product launch, which could have serious financial implications to a patentee bringing a new product to Canada.

Given the limited period of patent protection on our products, one of the critically important key success criteria has become the time to market, which may be adversely affected by this new policy. It is impractical to presume that we could finalize the price earlier than we have in the past, given the complexities associated with determining price

in the Canadian market. Our launch price is set in accordance with the latest information on competitive pricing in Canada, including the price at which our various affiliates launch in other markets and on assessment of the perceived value of the medicine, and ultimately requires not only local senior management approval, but also approval of our head office. Obtaining head office approval can be a protracted process, particularly in today's climate of concern regarding global implications of local pricing policies.

There are also confidentiality and timing issues to be addressed with respect to this proposed amendment. It is Wyeth's contention that the value for medicine evidence and announcement of pricing for new drugs to customers and drug plan payers/administrators must be packaged together, in order that the rationale and justification for the launch price be put into proper perspective. It is unlikely that the value for medicine evidence and messaging will be finalized 60 days in advance of the product launch. Also, Wyeth is concerned that, given PMPRB's increasingly close working relations with the provincial drug plans, pricing information shared with PMPRB may find its way into the hands of the drug plan managers, and the opportunity to link the value for medicine evidence and the proposed launch price may be compromised.

Determination of final pricing prior to granting of NOC is also impractical, as we do not necessarily know what the approved indications are ultimately going to be for the product, as negotiation of the wording of the product monograph and other labeling is one of the final steps before obtaining NOC from Health Canada. As the approved indications are critical to identifying the appropriate comparators to be used in determining a price that would be accepted by PMPRB, there may be last minute revisions required to the price to reflect any changes and still remain within guidelines. If this occurs, would we be required to amend our advance pricing and wait another 60 days prior to launch? If so, this could again necessitate a delay in launch with the inherent financial consequences in order to satisfy this new proposed regulation.

The advance notice of proposed pricing is also impractical when applied to product brought into Canada pre-commercialization, specifically under a Health Canada-approved Special Access Program ("HC-SAP"). As this could occur well before NOC is anticipated, the likelihood of having even an estimated launch price is extremely unlikely, which would make compliance with this proposed regulation impossible. Furthermore, as in these special circumstances there is usually an urgent medical requirement for the medicine to be available immediately, making the patient wait 60 days for the medicine while we await PMPRB approval is unconscionable.

Wyeth cannot support the intent or the planned implementation of this proposed amendment.

Sec. 3.2: Notification of Proposed Price Increase

There is no current legal requirement in either the Patent Act or the Regulations requiring patentees to provide advanced notification of price increases to PMPRB. In fact, PMPRB's mandate under the Patent Act is to review " the price at which the medicine is being or has been sold", not to regulate or obtain advance information on potential future prices. Wyeth believes that the existing reporting requirements, the submission of sales data within 30 days of the end of each 6 month reporting period, is adequate and timely to address the price review requirements of PMPRB. An amendment to the regulations that requires "… any proposed increase to the price of the medicine, for any class of customers in any market in Canada, shall be communicated to the Board at least 120 days before the effective date of the intended price increase", extends beyond the mandate of the PMPRB, that is, to ensure the prices of patented medicines in Canada are not excessive. Furthermore, the addition of an new layer of reporting requirements would add to the workload of an already heavily burdened patentee, as well as to the workload of the staff resources available to PMPRB, without addressing their mandate to review historical, rather than prospective, pricing of patented medicines.

It is also unclear how prior submission of prices would add value to the PMPRB price review process. The determination of excess revenues is based upon actual net units sold and net revenues generated, not projections. The current regulations clearly set out the parameters for allowable price increase, and it is the Board's responsibility to ensure that these parameters are not exceeded. Ex-factory pricing is, on its own, a meaningless number to be reviewed, as it may or may not be reflective of the actual selling price, given that discounts, rebates or other allowable deductions may be factored into the net revenues, thereby reducing the actual average selling price below the ex-factory price. In addition, actual ASP is impacted by the timing of allowable increases by the administrators of the public drug benefit plans. Wyeth contends that the existing requirement of reporting actual sales data within 30 days of the end of each 6-month reporting period provides more appropriate data, is received in a timely manner, and is adequate to facilitate the review of prices by PMPRB.

As with the discussion concerning advance notification of proposed pricing for new patented medicines, there are also confidentiality and timing issues to be addressed with respect to this proposed amendment. In addition, for commercially marketed drugs, it is an absolute necessity that price strategy be carefully guarded, due to the very competitive nature of the pharmaceutical industry. Wyeth is concerned that pricing information shared with PMPRB may find its way into the public domain, resulting in the patentee being placed in an untenable and disadvantageous competitive position.

This proposed amendment is also impractical from a compliance perspective, as the assessment of Competitive Intelligence and market conditions are key components in any price increase scenario. Typically, such activities are being conducted virtually up to the time any price increases are finalized, and, given the competitive pharmaceutical market,

actual price increase are not likely to be known with any certainty 120 days in advance of implementation, in order to be able to submit anything meaningful to the PMPRB.

Wyeth cannot support the intent or the planned implementation of this proposed amendment.

Sec. 3.3: Details on the Calculation of Net Price and Net Revenues

This proposed amendment states "… any amounts used in the calculation must be identified and reported on the appropriate form." Wyeth Canada is concerned that, without the benefit of seeing the proposed revised forms, the implementation of this proposed amendment may add to the significant reporting burden already imposed upon patentees.

In principal, Wyeth does not object to the implementation of measures which enhance transparency; however, we cannot support this proposed amendment without reviewing the specific forms being proposed, as well as obtaining a clearer understanding as to how the provision will make the price review process more efficient and not simply increase the burden on both patentees and Board staff.

Sec. 3.4: Product Monograph / Draft Monograph

Wyeth Canada is generally supportive of this proposed change, and, in fact, routinely submits either the Product Monograph or most current Draft Monograph as part of any New Drug Submission filing with PMPRB. However, Wyeth does have reservations concerning patented medicines sold in Canada under a Health Canada-approved Special Authorization Program . Such products are typically sold pre-NOC, and often there may never be any intent to commercially launch such products into the Canadian marketplace. Consequently, there may be no Canadian Product Monograph, draft or approved in order to be able to comply with this proposed regulation.

Wyeth Canada believes that the proposed amendments must be modified to reflect the potential non-availability of a Canadian draft or approved Product Monograph for patented medicines sold under an HC-SAP.

Sec. 3.5: Recognition of Electronic Signatures

Wyeth Canada fully supports this proposal, and looks forward to expanding the extent to which it already uses electronic filing of submissions to PMPRB.

Sec. 3.6: Filing Requirements for Veterinary Patentees

Wyeth Canada fully supports these proposed 'housekeeping' amendments.

Sec. 3.7: Editorial Corrections

Wyeth Canada fully supports these proposed amendments.

PART III: SUMMARY

Wyeth Canada appreciates the opportunity to make this submission. In Wyeth's assessment, several of the proposed amendments clearly address the Board's objective of modernizing "…some areas [of the Regulations] to better reflect the information needs of the PMPRB to carry out its responsibilities". Wyeth has identified these proposed amendments (Sec. 3.5 – 3.7) in this submission, and fully supports the Board's initiatives to implement them as quickly as practical.

Wyeth has also identified in this submission concerns with certain proposed amendments (Sec. 3.1 – 3.4). where it is seeking additional clarification. Wyeth fails to understand how the implementation of these proposed amendments will assist the Board in accomplishing its mandate of ensuring prices of patented medicines in Canada are not excessive, .beyond the reporting requirements which already exist in the Patent Act and Regulations. It is Wyeth's opinion that the implementation of these amendments will: a) promote inefficiencies in the Board's review process, as the Board's mandate is to review historical prices, not prospective prices; b) increase the reporting burden on patentees, as well as the review workload on Board staff, with no obvious benefits; c) create significant compliance issues, as the requested pricing information is not typically available within the lead times dictated by the proposed amendments; d) potentially delay the launch of a new patented medicine, thereby imposing a financial hardship on the patentee and delaying access to a medical treatment advance to patients in need; e) increase the likelihood that the packaging of the rationale and justification for the proposed price increases and the value for medicine evidence will be compromised; f) increase the risk that the release of sensitive pricing information into the public domain will not be in the patentees best interest; g) result in the Patent Act and the Regulations being in direct contradiction as to reporting requirements imposed on patentees.

Wyeth Canada strongly recommends that the Board revisit the identified proposed amendments for the purpose of clarifying what value these amendments offer to the price review process beyond the reporting requirements already embodied in existing legislation. Wyeth also encourages an additional commentary period to facilitate meaningful discussions between the Board and its stakeholders on these matters.

Date: April 14, 2005